DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

EDDA Technology
% Mr. Daniel Kamm
Regulatory Engineer
5 Independence Way
PRINCETON NJ 08540

Re: K141745
Trade/Device Name: IQQA-BodyImaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 22, 2014
Received: September 29, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*

K141745

Device Name
IQQA-BodyImaging Software

Indications for Use *(Describe)*
IQQA-BodyImaging is a PC-based, self-contained, non-invasive image analysis software application for reviewing body imaging studies (including thoracic, abdominal and pelvic) derived from CT and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation, and reporting of body imaging studies and physician-identified lesions.

The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of such lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up.

The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**EDDA Technology 510(k) Summary K141745**
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**Princeton, NJ 08540**
**Tel: 609-919-9889**
**Fax: 609-919-9779**
**Contact: Xiaolan Zeng, Executive Vice President**
**Date prepared: September 22nd, 2014**

1. Identification of the Device:
   Proprietary – Trade Name: IQQA-BodyImaging Software
   Classification Name: System, Image Processing, Radiological, Product Code LLZ
   Common/Usual Name: Radiological Image Processing System

2. Substantially equivalent legally marketed devices:

| Manufacturer | Name of the Predicate Device | FDA 510(k) Number | FDA Clearance Date |
|---|---|---|---|
| GE Medical Systems | Volume Viewer Plus | K041521 | 06/22/2004 |
| Mevis Medical Solutions | Visia Oncology | K120484 | 03/27/2012 |
| EDDA Technology | IQQA-Liver Multimodality | K131498 | 07/25/2013 |
| Intio | ClearStart SVM | K113541 | 12/16/2011 |

3. Indications for Use (intended use):

   IQQA-BodyImaging is a PC-based, self-contained, non-invasive image analysis software application for reviewing body imaging studies (including thoracic, abdominal and pelvic) derived from CT and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation, and reporting of body imaging studies and physician-identified lesions. The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of such lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up. The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.

4. Description of the device:

   The IQQA-BodyImaging Software is a self-contained, non-invasive radiographic image analysis application that is designed to run on standard PC hardware. The image input is DICOM. The data utilized is derived from CT and MR scanners, and includes thoracic/abdominal/pelvic images.

   Combining image processing, viewing and reporting tools, the software supports the visualization, evaluation and reporting of body imaging scans and physician identified lesions. Viewing tools include 2D original DICOM image viewing, window level adjustment, pre-

defined optimized window level setting, synchronized viewing of multi-phase datasets or volumes from multiple time-points, MPR (orthogonal, oblique and curved), MIP and MinIP, volume rendering. Analysis and evaluation tools include automatic/interactive segmentation of structures utilizing user input of seeding points and bounded boxes, interactive labeling of segmented areas, user tracing and interactive editing, quantitative measurement derived from segmentation and labeling results, and the measurement of distance between physician specified structures and landmarks. Reporting tools in the software automatically assemble information including physician identified lesion locations, measurement information, physician-input lesion characterization, lesion snapshot images across multi-phases or multiple time-points, information of organ segments and vessels/ducts/airways, and illustrative snapshots of the GUI taken by physicians, for physician's confirmation and further diagnosis and patient management note input.

The IQQA-BodyImaging software supports a workflow based on automated registration for viewing and analyzing multiphase or multiple time-point volume datasets. The software automatically matches the spatial location of original DICOM images across contrasted multiphases or multiple time-points, and with physicians' interactive adjustment, to enable synchronized viewing of datasets simultaneously. Physician may also activate the temporal movie display of selected slice locations across multi-phases to aid visualization and evaluation.

After identifying and marking lesions on 2D image display, physicians can either manually trace lesion boundary or activate automated tools to segment lesion. The software further includes tools for interactive segmentation and interactive labeling of organ segments and vascular/ductal/airway structures (such as liver lobes, lung lobes, major branches of vessels/ducts/airways), thus facilitating the visualization of spatial relationship between suspicious lesions and specified anatomical structures/landmarks.

The software provides functionalities for interactive adjustment of user-defined margin size around the lesion, interactive definition of virtual resection plane, interactive definition of virtual needle path to lesion and local zone, regional analysis of lesions with respect to size, shape, position, margin, and enhancement pattern etc, synchronized view of lesion and information between planning/baseline study and monitoring/follow-up studies, thus providing information to support physician's to evaluation of physician-identified lesions as well as treatment planning, monitoring and follow-up assessment.

The software is designed for use by trained professionals only (physicians, radiologists, surgeons, hospital technicians etc). Physicians make all final diagnosis and patient management decisions.

5. Comparison with predicate devices – IFU and Technological characteristics (Next page)

| | *Device of 510(k) submission:* **IQQA-BodyImaging Software (version 1.0) K141745** | *Predicate Device:* **Volume Viewer Plus K041521** | *Predicate Device:* **Visia Oncology K120484** | *Predicate Device:* **IQQA-Liver Multimodality Software K131498** | *Predicate Device:* **ClearStart SVM K113541** |
|---|---|---|---|---|---|
| Manufacturer | EDDA Technology | GE Medical System | Mevis Medical Solutions | EDDA Technology | Intio |
| Indications for Use | IQQA-BodyImaging is a PC-based, self-contained, non-invasive image analysis software application for reviewing body imaging studies (including thoracic, abdominal and pelvic) derived from CT and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation, and reporting of body imaging studies and physician-identified lesions.<br><br>The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of such | Volume Viewer Plus is medical diagnostic software that allows the processing, review, analysis and communication of 3D reconstructed images and their relationship to originally acquired images from CT, MR, X-Ray Angio and PET scanning devices. The combination of acquired images, reconstructed images, annotations and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery and treatment planning. | Visia Oncology is a medical software application intended for the visualization of images from a variety of image devices. The system provides viewing, quantification, manipulation, communication, and printing of medical images. Visia Oncology is a noninvasive image analysis software package designed to support the physician in routine diagnostic oncology, staging and follow-up. Flexible layouts and automated image registration facilitate the synchronous display and navigation of multiple datasets for viewing data and easy follow-up comparison. The application provides a range of interactive tools specifically | IQQA-Liver Multimodality is a PC-based, self-contained, non-invasive image analysis software application for reviewing multiphase images derived from various sources (e.g. CT scanners, MR scanners). Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation and reporting of liver and physician-identified lesions.<br><br>The software supports a workflow based on automated image registration for viewing and analyzing multiphase volume datasets. It includes tools for interactive segmentation and labeling of liver segments and vascular structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane, and allows for regional volumetric analysis of such lesions in | The INTIO ClearStartSVMTAI system is a self-contained image analysis desktop workstation addressing the needs of physicians performing diagnostic oncologic imaging, treatment planning, and post-procedure or systemic therapy follow-up assessment. ClearStartSVMNI provides semi-automated tools for segmentation of suspicious lesions including primary and metastatic lung and liver tumors, and lymph node assessment using non-contrast and contrast CT images. Following lesion segmentation, ClearStart.SVMTM'Sautomated1 volumetric, RECIST and WHO lesion measurements provide the user with data on the time-course of patient response to therapy. An on-board large disk storage capacity allows the user to easily track each patient's CT data from initial diagnosis through therapeutic interventions and follow up exams and includes a reporting package to aid in the assessment of response to therapy.<br><br>The system is password protected so that only the above mentioned trained medical |

| | *Device of 510(k) submission:* **IQQA-BodyImaging Software (version 1.0) K141745** | *Predicate Device:* **Volume Viewer Plus K041521** | *Predicate Device:* **Visia Oncology K120484** | *Predicate Device:* **IQQA-Liver Multimodality Software K131498** | *Predicate Device:* **ClearStart SVM K113541** |
|---|---|---|---|---|---|
| | lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up.<br><br>The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM. | | designed for segmentation and volumetric analysis of findings. The integrated reporting helps the user to track findings and note changes, such as shape or size, over time. | terms of size, position, margin and enhancement pattern, providing information for physician's evaluation and treatment planning.<br><br>The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM. | professionals are authorized users. |
| Image Modality Input | CT, MR | CT, MR, PET, PET/CT | From various sources such as CT | CT, MR | CT |
| Imaging Coverage | Thoracic, Abdominal, Pelvic | Thoracic, Abdominal, Pelvic,Neuro. & more | Oncology coverage in general | Abdominal | Thoracic, Abdominal |
| Segmentation & volumetric analysis of structures of interest | Yes | Yes | Yes | Yes | Yes |
| Tracking through multiple images | automated image registration | Not specified | automated image registration | automated image registration | allows user to track each patient's CT data from initial diagnosis through therapeutic interventions and follow up exams |
| Used by | for use by trained professionals, including physicians and technicians | clinician, referring physicians | physician | for use by trained professionals, including physicians and technicians | trained medical professionals |
| Hardware Configuration | standard PC hardware | standard PC hardware | standard PC hardware | standard PC hardware | standard PC hardware |
| User Interface | A graphical user interface for users to interact with the software, select tools and drive workflow | A graphical user interface for users to interact with the software, select tools and drive workflow | A graphical user interface for users to interact with the software, select tools and drive workflow | A graphical user interface for users to interact with the software, select tools and drive workflow | A graphical user interface for users to interact with the software, select tools and drive workflow |

IQQA-BodyImaging software has the similar intended use and technological/functional features as the predicate devices in providing tools and workflow designs to support physician users to visualize and evaluate DICOM images of selected patient studies; supporting physicians to evaluate, quantify, and document physician-identified structures of interest; being used by physicians to support own patient management decision making.

The IQQA-BodyImaging device has no patient contacting materials and is utilized only by trained professionals. The trained professionals, providing ample opportunity for competent human intervention interpret images and information being displayed. They are competent to determine whether the images provide information that can be useful in the decision of a diagnosis and patient management. Physicians make all final diagnostic and patient management decision.

IQQA-BodyImaging and predicate devices are substantially equivalent in the areas of technical characteristics, principles of operation, and functional features. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices.

6. Safety and Effectiveness:

The IQQA-BodyImaging labeling contains instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via the company's design control and risk management procedures. Potential hazards are controlled via software development and verification and validation testing.

7. Testing Information and Performance:

All product specifications were verified and validated. Testing was performed according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

On the segmentation and measurement tools, experimental results on simulated images containing structures of interest (including ellipsoid, crescent, and cylinder shapes) to study measurement accuracy showed less than 1.5% in volume measurement difference as compared with the ground truth. In addition, to study intra-observer consistency when using the IQQA-BodyImaging interactive segmentation and measurement tools, retrospective clinical patient studies of CT and MR modalities for the thoracic, abdominal and pelvic body parts were used -- the mean volume measurement differences by two physicians were 0.4%, 1.5% and 2.5%, respectively.

On the registration tools, experiments involving phantom image pairs scanned at different times with different positioning and orientations, and retrospectively collected patient studies scanned at different times during clinical practice were conducted. The results showed a mean interactive registration error of 0.2394mm with a standard deviation of 0.2261mm on phantom studies scanned at different times with different positioning and orientations, a mean initial automated

registration error of 0.5594mm with a standard deviation of 0.5448mm on patient studies with synthetic deformations, and a mean interactive registration error of 0.5388mm with a standard deviation of 0.7150mm on retrospective patient studies that are scanned at different times during clinical practice.

Additionally, to supplement the software validation for IQQA-BodyImaging, the company has conducted software testing at two clinical sites. The purpose of the testing is to have physicians use the IQQA-BodyImaging software application to review CT and MR body imaging scans, validate major functionalities provided by the system, and provide feedback along the line of the intended use of the system.

## 8. Conclusion

The IQQA-BodyImaging software package has the same intended use as the predicate devices. Test results demonstrate that the device is safe, effective, and does not raise any new potential safety risks. In all material respects, the IQQA-BodyImaging software tool is substantially equivalent to the predicate devices.